

REMARKS

Claims 1-54 are currently pending. Applicants gratefully acknowledge that claims 1-8 are allowed.

Applicants also acknowledge that the Examiner has withdrawn the obviousness-type double patenting rejection.

Rejection of Claims 9-54 under 35 U.S.C. § 112, First Paragraph

Claims 9-54 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the specification sufficiently enables the addition of proline and glutamine to a composition of riboflavin and/or riboflavin derivative, but concludes that the specification does not reasonably provide enablement for any composition formulation additive.

Applicants would like to point out where there is support in the specification for composition formulation additives in addition to riboflavin and/or riboflavin derivatives.¹ The specification provides support for the addition of the following composition formulation additives:

antibiotics (at col. 2, line 36):

“It has been unexpectedly found that the combined use of riboflavin and/or a riboflavin derivative and an antibiotic develops a so-called synergism over those achieved by their single use. As a result, such combined use gives an important effect that the amount of the antibiotic to be used is decreased to a significant extent. Thus, the present invention relates to an immunopotentiating and infection protective agent comprising riboflavin and/or a riboflavin derivative and an antibiotic.”

water-soluble polymers or lecithins (at col. 2, line 46):

“Further, it has been unexpectedly found that the combined use of riboflavin and/or a riboflavin derivative and a water-soluble polymer or lecithin enhance the infection protective effect of riboflavin and/or a riboflavin derivative. Therefore, the present

¹ Applicants previously made this showing in the Request for Continued Examination under 37 C.F.R. § 1.114 filed by Applicants on 7/19/2004.

invention relates to an immunopotentiating and infection protective agent comprising riboflavin and/or a riboflavin derivative and a water-soluble polymer or lecithin.”

vaccines (at col. 2, line 54):

“Further, it has been unexpectedly found that the combined use of riboflavin and/or a riboflavin derivative and a vaccine exhibits a so-called synergism over the immunopotentiating and infection protective effects achieved by their single use. Thus, the present invention relates to a vaccine preparation comprising riboflavin and/or a riboflavin derivative and a vaccine.”

proline and glutamine (at col. 2, lines 25-35):

“As described above, proline and glutamine have an action to potentiate immune function. However, it has been unexpectedly found that the combined use of riboflavin and/or the riboflavin derivate with proline and/or glutamine according to the present invention synergistically enhances the action to potentiate immune function. Therefore, the present invention relates to an immunopotentiating and infection protective agent comprising riboflavin and/or a riboflavin derivate and praline and/or glutamine.”

Furthermore, composition formulation additives are disclosed and Applicants respectfully submit, enabled, in the working examples:

Example 2 and Tables 2 and 3 disclose the effect of the addition of proline and glutamine to the compositions of riboflavin and/or riboflavin derivatives.

Example 4 and Table 5 disclose the effect of the addition of antibiotic to compositions of riboflavin and/or riboflavin derivatives.

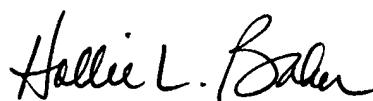
Example 5 and Table 6 disclose the effect of the addition of a water-soluble polymer to the compositions of riboflavin and/or riboflavin derivatives.

Example 6 and Table 7 disclose the effect of the addition of lecithin to the compositions of riboflavin and/or riboflavin derivatives.

In summary, the working examples demonstrate the enhanced effect the composition formulation additives have on the immune system when added to a composition with riboflavin and/or riboflavin derivatives. For all of the foregoing reasons as detailed in this response, Applicants maintain that claims 9-54 are enabled under Section 112, first paragraph.

Accordingly, Applicants respectfully request that the Examiner reconsider the rejection of claims 9-54 under 35 U.S.C. § 112, first paragraph, in view of these remarks and the description in the specification, and to withdraw it.

Respectfully submitted,



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